Abstract

Objective: Previous research has demonstrated the value of endometrial preparation before hysteroscopic procedures. Duration of endometrial preparation prior to hysteroscopic sterilization has not yet been evaluated. The aim of our study is to evaluate the relationship between hormonal endometrial preparation duration and the placement success rate with Essure hysteroscopic sterilization.

Study Design: An institutional review board (IRB) approved retrospective cohort study of all women who underwent hysteroscopic sterilization from August 2003 to April 2010 in an urban academic center in Chicago, Illinois was performed. Exclusion criteria included insufficient or incomplete data. Variables including Essure placement success, type and duration of endometrial preparation, demographic factors and hysterosalpingogram (HSG) occlusion rates were compared using chi-square and co-relational analyses.

Results: Overall, the Essure placement success rate was 91.5% (226/247). Race, parity, body mass index (BMI), previous surgical history and type of hormonal endometrial preparation did not significantly affect the placement success rate. Women with endometrial preparation (n=216) were significantly more likely to experience successful placement compared to those with no preparation (n=31; p<.005). When comparing Essure placement success rates in patients with 30 days or less (n=49) compared to those that underwent more than 30 days of preparation (n=167), there was no significant effect of duration of hormonal endometrial preparation on placement success rate (p=0.518).

Conclusion: This study supports the use of hormonal endometrial preparation prior to hysteroscopic sterilization and suggests that the duration of hormonal treatment does not affect the rate of successful Essure placement. Therefore, scheduling patients for Essure procedures within 30 days of initiating endometrial preparation is unlikely to deleteriously affect Essure placement success, but may instead lower costs and improve patient compliance. Further prospective studies are needed to validate these findings.

Keywords: Essure; Hysteroscopy; Tubal; Hormone; Endometrium

Introduction

The Essure device, a type of hysteroscopic sterilization, was approved by the FDA in 2002. This permanent contraceptive method involves the placement of nickel titanium alloy and stainless steel micro-inserts into the Fallopian tubes hysteroscopically. The cumulative effectiveness at 5 years is 99.8 % and placement success rates have been reported to range from 81% to 98% [1-5]. Reported placement failure reasons have included obesity, anxiety, difficult uterine cavity access, non-identification of tubal ostia and cervical stenosis. Some studies suggest that the most common factor for Essure placement failure is poor visualization of the tubal ostia [6,7]. According to Panel et al. [7] the failure rate was increased sevenfold with poor visualization. Sinha et al. [2] demonstrated that higher success rates were noted in patients in whom Essure was performed in the proliferative phase of the menstrual cycle. Thus, for adequate visualization, it is important to perform Essure when the endometrial lining is thin.

While it is recommended by the manufacturer to perform an Essure during the follicular phase of the menstrual cycle, this is not always feasible. An alternative for thinning the endometrial lining is the use of hormonal therapy. Endometrial glandular proliferation has been shown to be inhibited by endogenous progesterone in premenopausal women and markedly reduced in those receiving synthetic progestins [8,9]. Oral contraceptives also exert a predominant progesterone effect on the endometrium, inducing an arrest of glandular proliferation and subsequent endometrial atrophy [9]. Several studies have suggested that endometrial preparation prior to hysteroscopic procedures improves operative conditions [10]. According to Shawki et al. [11] endometrial pretreatment with medroxyprogesterone acetate prior to endometrial ablation or resection allowed better hysteroscopic visualization. Qato et al. [12] also demonstrated increased success rates with endometrial pretreatment with hormone therapy. The objective of our study is to evaluate the relationship between hormonal endometrial preparation duration and Essure placement success rates.

Abbreviations: IRB: Institutional Review Board; HSG: Hysterosalpingogram; BMI: Body Mass Index Result

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Materials and Methods

A University of Illinois at Chicago institutional review board (IRB) approved retrospective chart review was conducted for all patients who were scheduled to undergo an Essure procedure at the University of Illinois Medical Center at Chicago, an urban academic center, from August 2003 to April 2010.

Essure procedures were performed by general obstetrics and gynecology attendings that performed at least one Essure per month. All patients received 30mg of IV ketorolac within 30 minutes of the procedure. All Essure procedures were performed in the operating room and most patients received monitored anesthesia care (152 patients, 56%). The remainder of procedures were performed under general anesthesia with a laryngeal mask airway (75 patients, 27.7%), general anesthesia with endotracheal tube placement (40 patients, 14.8%) and spinal anesthesia (4 patients, 1.5%).

Data analyzed included number of failed procedures, number of patients receiving versus those not receiving hormonal endometrial preparation, type of preparation administered and duration of hormonal preparation. Other data collected comprised of age, race, BMI, parity, prior surgery and hysterosalpingogram (HSG) occlusion rates. Operative reports were reviewed to determine whether or not the Essure was successfully inserted. Successful placement of Essure was defined as bilateral placement of coils according to the manufacturer’s instructions. Duration of endometrial hormonal preparation was calculated from time of initiation of hormonal preparation to day of procedure and classified as more or less than 30 days, or approximately the length of a typical menstrual cycle. Subjects with incomplete records were excluded. Statistical analysis utilized Chi-square test and logistic regression models. Probability (p) values of <.05 were considered statistically significant.

Results

Over the study period, a total of 271 women had Essure placement scheduled as their initial procedure for permanent sterilization at the University of Illinois Medical Center at Chicago. Twenty-four women were excluded due to missing data in the medical records. Of the 247 women, 216 (87.4%) had received hormonal preparation while 31 (12.6%) patients did not receive hormonal preparation (Figure 1). The hormonal preparation group included women who had received medroxyprogesterone acetate intramuscular injections (1M DepoProvera, 53%), oral contraceptive pills (OCPs, 30%), the etinyllestradiol/etonogesterel ring (Nuvating, 11%), OrthoEvra patch (4%) or the levonorgestrel intrauterine device (Mirena IUD, 2%) for durations ranging from 4 days to 12 years prior to their Essure procedure.

The median patient age in this study was 32 years [range 21-48 years]. The majority of patients were multiparous (97.8%), black (71.7%) and had a BMI greater than 30 (82.6%). Analysis of demographic variables revealed no statistical differences between the endometrial preparation and non-preparation groups with regards to race (p=0.608), multiparity (p=0.142), BMI greater than 30 (p=0.378) or previous surgery (p=0.634) (Table 1). In addition, there was no significant difference in Fallopian tubal occlusion rates at 3 months on hysterosalpingogram between the endometrial preparation and non-preparation groups (p=0.408).

Table 1: Demographics in endometrial versus no endometrial preparation groups.

<table>
<thead>
<tr>
<th></th>
<th>Total (N%)</th>
<th>Preparation</th>
<th>No preparation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>177 (71.7)</td>
<td>160</td>
<td>17</td>
<td>0.608</td>
</tr>
<tr>
<td>Hispanic</td>
<td>48 (19.4)</td>
<td>40</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>13 (5.3)</td>
<td>10</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>9 (3.6)</td>
<td>6</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Multiparity</td>
<td>241 (97.8)</td>
<td>210</td>
<td>31</td>
<td>0.142</td>
</tr>
<tr>
<td>BMI &gt;30</td>
<td>204 (82.6)</td>
<td>182</td>
<td>22</td>
<td>0.378</td>
</tr>
<tr>
<td>Previous Surgery</td>
<td>100 (40.5)</td>
<td>90</td>
<td>10</td>
<td>0.634</td>
</tr>
</tbody>
</table>

In total, 21 (8.5%) Essure procedures were unsuccessful and converted to laparoscopy (n=17) or mini-laparotomy (n=4) for sterilization or were aborted completely (n=3). Reasons for failure included poor visualization due to “fluffy” or thick endometrium (n=10), tubal spasm or occlusion with inability to pass the Essure device (n=2) or device malfunction or failure (n=3). Reasons for failure were not documented for 6 of the Essure failures. In the hormonal preparation group, the 12 (5.5%) failed Essure procedures included patients who used the following hormonal methods: DepoProvera (n=8), OCPs (n=3) and the Mirena IUD (n=1). The duration of endometrial preparation in this group ranged from 8 days to 12 years, of which 9 of the 12 patients had hormonal treatment between 8 and 55 days. In the non-hormonal group, 9 Essure procedures were unsuccessful. Of these patients, 8 underwent a laparoscopic tubal ligation and 1 underwent a mini-laparotomy after a failed laparoscopic sterilization.

The successful Essure placement rate for the endometrial preparation group was statistically significantly higher at 94.4% versus 72.7% in the no preparation group (p-value < 0.001) (Figure 1). When comparing various endometrial preparation

methods, there was no difference in the rate of successful Essure placement (p-value= 0.933) between types of hormonal treatments including Depoprovera, OCPs, Nuvaring, OrthoEvra patch and Mirena IUD. In the endometrial preparation group, 49 (22.6%) patients underwent 30 days or less of preparation compared to 167 (77.3%) patients who underwent more than 30 days. There was no significant difference in Essure placement success rates between these two groups (95.9% versus 93.9%; p-value=0.518).

Discussion

The Essure procedure has become an increasingly attractive form of permanent sterilization for clinicians and their patients. Adequate visualization of tubal ostia is essential for successful placement of this hysteroscopic sterilization device. Our study reconfirms findings in a previous study at our institution that the use of hormonal preparation prior to hysteroscopic sterilization increases the rates of placement success and further suggests that duration of endometrial preparation does not affect the success rate of Essure placement [12]. Additionally, given that the Essure procedure may be considered as a type of operative hysteroscopy, the findings of this study are consistent with prior studies demonstrating beneficial use of hormonal pretreatment for operative hysteroscopy [10,11].

Though we acknowledge that timing of the menstrual cycle in relation to timing of the Essure procedure can potentially mitigate procedure success, this variable was not included in our data collection due to inconsistencies in medical record documentation. Nevertheless, Essure procedures at our institution were typically performed within the first two weeks of the menstrual cycle. Although this study is limited by its retrospective design and small sample size, the findings from our study may still have important clinical implications. Hormonal endometrial preparation presents an alternative to timing the hysteroscopic sterilization procedure with patients’ menstrual cycles. In addition, the duration of hormonal preparation does not appear to affect the Essure placement success rate. Thus, physicians may consider scheduling patients for Essure placement soon after initiating endometrial preparation. By allowing a more flexible and a shorter interval between endometrial preparation initiation and procedure, this may then improve patient compliance with endometrial preparation use while decreasing the risks of undesired pregnancy. The findings from our study not only can be applied to hysteroscopic sterilization, but can also potentially be applied to operative hysteroscopy in general, though further investigation is warranted. Future prospective studies are needed to determine the optimal duration of endometrial preparation and the impact of type of hormonal preparation on the rate of success of Essure placement.

Conclusion

This study supports the use of hormonal endometrial preparation prior to hysteroscopic sterilization and suggests that the duration of hormonal treatment does not affect the rate of successful Essure placement. Therefore, scheduling patients for Essure procedures within 30 days of initiating endometrial preparation is unlikely to deleteriously affect Essure placement success, but may instead lower costs and improve patient compliance.

References